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- (71) Applicant (for all designated States except US): CAMP-INA B.V. [NL/NL]; Hogeweg 9, NL-5301 LB Zaltbommel (NL).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): ELLISON, Mark, Jason, Heath [GB/NL]; Jan Heinstraat 2a, NL-5211 TD 's Hertogenbosch (NL). LAMBREGTS-VAN DEN HURK, Theodora, Antonia, Maria [NL/NL]; Generaal v. Vlij-menstraat 5, NL-5463 CH Veghel (NL).
- (74) Agent: VAN SOMEREN, Petronella, Francisca, Hendrika, Maria; Amold & Siedsma, Sweelinckplein 1, NL-2517 GK The Hague (NL).

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Published:

- with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: EXCIPIENT FOR USE IN DRY POWDER INHALATION PREPARATIONS

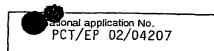
(57) Abstract: The present invention relates to an excipient for dry powder inhalation preparations comprising granules made of primary carrier material, which granules break down during inhalation in such a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger determined by the antrone reaction of at least 5%. Such excipients are for example obtainable by granulating a primary carrier material in a fluid binding agent and drying the granules thus obtained. The invention further relates to a method of preparing the excipient, to the use of the excipient and to dry powder inhalation preparations comprising the excipient.





									
A. CLASS IPC 7	SIFICATION OF SUBJECT MATTER A61K9/16								
According t	According to International Patent Classification (IPC) or to both national classification and IPC								
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Category •	Citation of document, with indication, where appropriate, of the re	elevant passages	Relevant to claim No.						
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Furthe	er documents are listed in the continuation of box C.	Patent family members are listed in	annex.						
*Y taler document published after the international filing date or priority date and not in conflict with the application but clied to understand the principle or theory underlying the invention. *E' earlier document but published on or after the international filing date *L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another cliation or other special reason (as specified) *O' document referring to an oral disclosure, use, exhibition or other means *P' document published prior to the international filing date but later than the priority date claimed *I' taler document published after the international filing date or priority date and not in conflict with the application but clied to understand the principle or theory underlying the invention *Coument of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document is combined with one or more other such document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *A' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is combined with one or more other such document is combined with one or more other such document is not priority date of the priority date and not in conflict with the application but clied to understand the principle or theory underlying the invention **C' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is combined with one or more other such document is combined with one or more other such document is not priority date and not in conflict with the application but clied to understand the principle or theory underlying the invention.									
	actual completion of the international search 3 January 2003	Date of mailing of the international search 03/02/2003	n report						
Vame and ma	ailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nt, Fay: (-31-70) 340-3016	Authorized officer							





Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)					
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:						
	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:					
	Claims Nos.: 10-25, 27 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:					
	see FURTHER INFORMATION sheet PCT/ISA/210					
	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).					
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)					
This Interr	national Searching Authority found multiple Inventions in this international application, as follows:					
1. A	as all required additional search fees were timely paid by the applicant, this International Search Report covers all earchable claims.					
	is all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment					
	f any additional fee.					
3. A	s only some of the required additional search fees were timely paid by the applicant, this International Search Report overs only those claims for which fees were paid, specifically claims Nos.:					
4. No	o required additional search fees were timely paid by the applicant. Consequently, this International Search Report is stricted to the invention first mentioned in the claims; It is covered by claims Nos.:					
Remark on	Protest The additional search fees were accompanied by the applicant's protest.					
	No protest accompanied the payment of additional search fees.					

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 10-25,27

Present claims 1-9, 26 relate to a product defined by reference to the following parameter(s):

"...break down in such a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger determined by the antrone reaction of at least 5%"

The use of these parameters in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT. It is impossible to compare the parameters the applicant has chosen to employ with what is set out in the prior art. The lack of clarity is such as to render a meaningful complete search impossible. Consequently, the search has been restricted to the subject matter of claims 10-25 and 27 Claims 1-9 and 26 furthermore relate to a product defined by reference to a desirable characteristic or property, namely that they break down in a certain manner during inhalation and determinable only by the twin stage impinger but to the in this connection unusal antrone reaction.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERMATIONAL SEARCH REPORT

nic-mation on patent family members

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